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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,177	02/18/2004	Rafail Zubok	SPINE 3.0-455 CIP CONT I	1815
530 7590 09/06/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 09/06/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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## Office Action Summary

Application No.

10/781,177

Applicant(s)

ZUBOK ET AL.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This action is in response to applicant's amendment received on 06/18/2007.

#### ***Allowable Subject Matter***

2. The indicated allowability of claim 6 is withdrawn in view of the newly discovered reference(s) to Willinger (U.S. Patent 6,213,055). Rejections based on the newly cited reference(s) follow.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5 and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 7,063,725) in view of Willinger (U.S. Patent 6,213,055).

Regarding claim 1, Foley discloses a device comprising a shaft having a handle at a proximal end and a head disposed at a distal end of the shaft. The head includes a first surface and a second surface that are spaced apart by a distance as discussed and shown in the previous office action. Regarding claim 2, Foley discloses a device wherein the first surface has a generally oval footprint area and the second surface also includes an area. Regarding claim 3, Foley discloses a device wherein at least one of the first surface includes a substantially convex area or the second surface includes a substantially flat area. Regarding claim 4, Foley discloses a device wherein at least one of the first surface is tapered towards the distal end or the second surface is tapered

towards the distal end. Regarding claim 10, Foley discloses a set of devices wherein each device comprises a shaft having a handle at a proximal end and a head disposed at a distal end of the shaft. The head includes a first surface and a second surface that are spaced apart. Foley further discloses the set of devices have head portions that differ in size (column 18 lines 42-55). Regarding claims 11 and 12, Foley discloses a set of devices wherein the heads of the devices differ in thickness by about 1 mm (column 7 lines 3-7). Regarding claim 13, Foley discloses a device wherein a square area of at least one of the trials differs from a head square area of at least one of the trials.

Regarding claim 14, Foley discloses a set of devices wherein at least one of a head thickness differs from a head thickness if at least one other of the trials and at least two heads of substantially the same head thickness have differing respective head square areas. Foley discloses a set of devices wherein the thickness of the heads of the devices have differing thicknesses. Regarding claim 15, Foley discloses a set of devices further including one or more disc replacement devices (column 18 lines 42-55). Foley fails to disclose a device further comprising at least one rib extending transversely away from the shaft and longitudinally along the shaft substantially to the head. Willinger teaches a device comprising a shaft having a handle at a proximal end and a head disposed at a distal end of the shaft further comprising at least one rib extending transversely away from the shaft and longitudinally along the shaft substantially to the head. Thus it would have been obvious to one having ordinary skill in the art to apply the technique of adding at least one rib extending transversely away from the shaft and longitudinally along the shaft substantially to the head as taught in Willinger to improve

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the device of Foley for the predictable result of forming a strong reinforcement and interconnection between the shaft and the head. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (2007).

Regarding claim 5, the combination of Foley and Willinger disclose a device wherein the head portion of the device includes a first surface and a second surface as discussed above. The combination of Foley and Willinger disclose the first and second surfaces of the head portion can be tapered at any angle. The combination of Foley and Willinger fail to disclose the first surface of the head portion to be tapered at an angle of about 5 degrees and the second surface of the head portion to be tapered at an angle of about 4 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Foley modified by Willinger wherein the head portion of the device with a first surface at an angle of about 5 degrees and with a second surface at an angle of about 4 degrees, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

5. Claims 7-9 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley (U.S. Patent 7,063,725) in view of Michelson (U.S. Publication 2003/0135279).

Regarding claims 7-9, Foley discloses a device comprising a shaft having a handle at a proximal end and a head disposed at a distal end of the shaft. The head includes a first surface and a second surface that are spaced apart by a distance as discussed and shown in the previous office action. Foley fails to disclose the invention

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further comprising a stop member. Michelson teaches a device including a shaft with a handle and a head portion further including a stop member (claim 7) that extends transversely at an anterior end of the head portion (claims 8 and 9). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the technique of adding a stop member that extends transversely at an anterior end of the head portion as taught in Michelson to improve the device of Foley for the predictable result of preventing over penetration of the device. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (2007).

Regarding claim 16, the combination of Foley and Michelson disclose a device as discussed above inherently capable of being used by a method comprising the steps of inserting a first of the trials into one of the intervertebral disc spaces to facilitate at least some distraction of the vertebral bones in a direction along a longitudinal axis of the spinal column and inserting a second of the trials into the intervertebral disc space to facilitate at least some further distraction of the vertebral bones along the longitudinal axis, where the second trial has a larger head thickness, measured substantially from the first surface to the second surface, than that of the first trial, where in the insertion steps include contacting the stop member with a portion of one of the vertebral bones. Regarding claim 17, the combination of Foley and Michelson disclose a device as discussed above inherently capable of being used by a method as discussed above further comprising the step of levering the handle of at least one of the first and second trials to facilitate the distraction of the vertebral bones. Regarding claim 18, the combination of Foley and Michelson disclose a device as discussed above inherently

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capable of being used by a method as discussed above further comprising the step repeating the insertion of further trials having larger and larger head thicknesses to facilitate the distraction of the vertebral bones to a target distance. Regarding claim 19, the combination of Foley and Michelson disclose a device as discussed above inherently capable of being used by a method as discussed above wherein the target distance is one that substantially maximizes the intervertebral space while substantially preserving annulus and ligaments associated with the vertebral bones. Regarding claim 20, the combination of Foley and Michelson disclose a device as discussed above inherently capable of being used by a method as discussed above further comprising the step of inserting an intervertebral disc replacement device into the intervertebral space after it has been distracted to the target distance.

### ***Response to Arguments***

6. Applicant's arguments filed 06/18/2007 have been fully considered but they are not persuasive. The applicant's argument that the Foley reference can not be modified by the teachings of the Michelson reference is not persuasive. The examiner has presented a new rejection combining the Foley reference modified by the teachings of the Michelson reference as discussed above. The Foley reference is capable of being modified by the teaching of the Michelson reference, since the teachings of Michelson improve the Foley reference with the predictable result of preventing over insertion of the device. The examiner has presented new grounds of rejection as discussed above and withdrawn the previously indicated allowability of claim 6 as discussed above.

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**Conclusion**

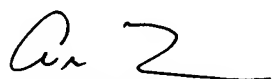
7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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